510(k) Summary – Levitronix PediMag Blood Pump

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations, Part 807, and in particular §807.92.

OCT - 8 2009

A. Application Information

Date Prepared:	October 2, 2009
Submitter's Name & Address:	Levitronix LLC 45 First Avenue Waltham, MA 02451
Contact Person:	Susan K. Hamann Regulatory Affairs Manager Ph: (781) 466-6553 Fax: (781) 622-5090 e-mail: shamann@levitronix.com

B. Device Information

Trade or Proprietary Name:	PediMag® Blood Pump
Common or Usual Name:	Centrifugal Pump
Classification Name:	Pump, blood, cardiopulmonary bypass, non-roller type (21 CFR 870.4360, Product Code KFM)
Performance Standard:	Performance standards do not currently exist for these devices. None established under section 514 of the Food, Drug and Cosmetic Act.

C. Legally Marketed Predicate Devices

- Levitronix CentriMag Blood Pump (K020271)
- Medtronic Bio-Pump BP-50 Centrifugal Blood Pump (K852807)

D. Device Description

The PediMag Blood Pump is a sterile, single-use, disposable, non-coated, polycarbonate centrifugal blood pump. The pump has a 14 ml priming volume. The pump inlet is on the rotational axis of the impeller whereas the pump outlet is perpendicular to the inlet and tangent to the outer diameter. Both the inlet and outlet ports include standard 1/4 inch barbed connectors for easy mating to

standard medical grade 1/4 inch tubing. The Pump is designed to move blood by centrifugal force created by the magnetically suspended rotating impeller.

E. Intended Use

The PediMag Blood Pump is indicated for use with the CentriMag Console and Motor to pump blood through a complete extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours) for surgical procedures such as a mitral valve reoperation. It is also indicated for use in extracorporeal support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, surgery of the vena cava or aorta, liver transplants etc.).

The PediMag Pump can generate a maximum pump flow equal to 1.5 liters per minute, limiting its use to pediatric patients.

The Levitronix PediMag Blood Pump is indicated for use only with the Levitronix CentriMag Console and Motor.

F. Technological Characteristics

The technological characteristics of the Levitronix PediMag Blood Pump are the same as the predicate devices.

G. Comparison to Predicate Devices

The Levitronix PediMag Blood Pump has an indication for use, design features, and functional characteristics which are substantially equivalent to the predicate devices. The device raises no new safety or effectiveness issues.

H. Summary of Performance Data

The Levitronix PediMag Blood Pump has successfully undergone functional testing demonstrating substantial equivalence to the predicate devices.

I. Clinical Performance

Clinical testing was not performed on this system.

J. Conclusion

The Levitronix PediMag Blood Pump is substantially equivalent to the Levitronix CentriMag Blood Pump (K020271) and to the Medtronic Bio-Pump BP-50 Centrifugal Blood Pump (K852807).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Levitronix LLC
c/o Ms. Susan K. Hamann
45 First Avenue
Waltham, MA 02451

OCT - 8 2009

Re: K090051
Trade/Device Name: Levitronix PediMag Blood Pump, Model 201-90052
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller-type cardiopulmonary bypass blood pump
Regulatory Class: Class III
Product Code: KFM
Dated: August 31, 2009
Received: September 1, 2009

Dear Ms. Hamann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090051

Device Name: Levitronix PediMag Blood Pump, Model 201-90052

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090051